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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,181	04/26/2001	Chris Sikorski	CER-298	9166

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,181

Applicant(s)

SIKORSKI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2003 has been entered.
2. The amendment filed April 24, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 1-6 and 14 have been canceled.
 - (B) Claims 7, 12, 16 and 18 have been amended.
 - (C) Comments regarding Office Action have been provided drawn to:
 - (i) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.
3. Claims 7-13 and 15-18 are pending in the case.
4. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, line 8, after "by weight", a comma should be inserted.

Claim 7, line 9, after "200 microns" a comma should be inserted.

Claim 7, lines 8-10, the passage "less than or equal to 200 microns and about 50% or more by weight greater than or equal to 20 microns" needs to state more clearly what feature the claim is referring to. Claims 8-11 are also rejected since these claims depend from Claim 7.

Claim Rejections - 35 USC § 103

6. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (US Patent No. 6,153,746) in view of Walsh (US Patent No. 5,980,971) or Giacobello (US Patent No. 4,127,944).

Applicants claim a process for making a dried porous, flake-shaped, uncomplexed agglomerated modified cyclodextrin product comprising drying an aqueous solution of uncomplexed modified cyclodextrin on a double-drum dryer; and recovering a dried porous, flake-shaped, uncomplexed agglomerated modified cyclodextrin product having a particle distribution wherein about 90% or more by weight of the particles have a particle size less than or equal to 200 microns and a particle distribution wherein 50% or more by weight of the particles have a particle size greater than or equal to 20 microns. Additional limitations in the dependent claims include hydroxypropylated beta-cyclodextrin selected as the cyclodextrin; specific revolutions per minute of the rotation of the drums on the drum-dryer; a specific pressure of the heated drums; and the solids content of the aqueous solution.

The Shah et al patent discloses sulfoalkyl ether cyclodextrins that are suitable for use as clathrating agents with drugs to provide complexes, which are useful in parenteral and other pharmaceutical formulation. The Shah et al patent provides a solution of sulfoalkyl ether cyclodextrin that can be isolated by a suitable drying technique that may be selected as vacuum drum drying (see column 3, lines 23-26). The sulfoalkyl ether cyclodextrin embraces the modified cyclodextrin product of the instant claims. See column 1, line 51 of the Shah et al patent whereby hydroxypropyl- β -cyclodextrin is disclosed as a well known cyclodextrin for forming inclusion complexes with hydrophobic molecules, which embraces the hydroxypropylated beta-cyclodextrin set forth in the claims. The instant claims differ from the Shah et al patent by claiming that the cyclodextrin is agglomerated and that the dryer thereof is a double-drum dryer. The Walsh patent shows that the interchangeability of single and double drum dryers is well known in the art. See column 6, first paragraph of the Walsh patent whereby drying apparatuses are disclosed that include single and double drum dryers. The paragraph further discloses the drum dryers being heated by steam from 10 to 150 pounds of

pressure per square inch, which covers part of the pressure set forth in the instant claims. The paragraph further explains that the thickness of the product can be varied by changing the settings of the drum dryer gap between the rolls, whereby a preferred product is a material of 0.0001 to 0.25 inches in thickness, which shows that it is within the skill of an artisan to obtain the distribution of the particles indicated in the instant claims.

The Giacobello patent teaches that the use of a drum dryer to improve the agglomeration of a dried product is well known in the art. See the text at column 10, 3rd paragraph of the Giacobello patent whereby a variation in the drying method is disclosed whereby a drum dryer can be enclosed in a vacuum chamber where the actual drying is carried out under reduced pressures. Giacobello discloses "that such variation will ordinarily hasten the drying process and in some instances lead to still further improved agglomeration of the dried product with consequent production of less fines while maintaining high absorbent properties". It is noted that the Shah patent does disclose the use of "vacuum drum drying" to produce the modified cyclodextrin product thereof (see column 3, line 26 of the Shah patent), which suggests an agglomerated product in view of the teachings of the Giacobello patent.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drum drying process conditions for preparing a dried modified cyclodextrin using the combination of the Shah et al and Walsh patents with a process condition whereby the drum dryer is enclosed in a vacuum chamber in view of the recognition in the art, as evidenced by the Giacobello patent, that such process condition allows for further improvement of agglomeration of dry products with production of less fines while maintaining high absorbent properties.

7. Claims 12, 13, 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Majid et al (US Patent No. 5,070,081) in view of Shah et al (US Patent No. 6,153,746).

Applicants claim a dried porous, flaked-shaped, uncomplexed agglomerated modified cyclodextrin product having about 90% or more by weight of said product with

Art Unit: 1623

a particle size of less than or equal to about 200 microns and about 50% or more by weight of said product with a particle size of greater than or equal to about 20 microns, wherein said product is made by a process comprising drying an aqueous solution of uncomplexed modified cyclodextrin on a drum dryer; and recovering a dried porous, flake-shaped, uncomplexed modified cyclodextrin product having said particle size.

The Majid et al patent shows that preparation of agglomerated cyclodextrin products are well known in the art (see abstract). See column 3, 4th paragraph of the Majid et al patent whereby it is explained that the size of the agglomerates can be varied by controlling the amount of water added and to a lesser degree the agitation. This passage embraces the particle size limitation set forth in the instant claims. The Majid et al patent further discloses that the starting cyclodextrin can be any of the alpha, beta or gamma forms known in the art (see column 2, lines 63-64), which covers the beta-cyclodextrin limitation set forth in instant Claim 15. With regard to the process limitations of the claimed product that is set forth in instant Claims 16 -18, applicants are reminded that process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. The instantly claimed invention differs from the Majid et al patent by claiming that the cyclodextrin product is a modified cyclodextrin.

The Shah et al patent shows that modified cyclodextrin product, such as hydroxypropyl- β -cyclodextrin (see column 1, line 51) and sulfoalkyl ether cyclodextrin (see column 2, line 59), are well known in the art. The Shah et al patent further shows that the modified cyclodextrin products are suitable for use as clathrating agents with drugs to provide complexes, which are useful in parenteral and other pharmaceutical formulations.

With regard to the description of the agglomerated modified cyclodextrin product being porous and flake-shaped, the following comment is provided. There is a distinction between a new article of commerce and a new article, which is patentable. Any change in form may render an article new in commerce. But to be patentable it must be more efficacious or possess new properties by a combination with other ingredients and not merely a change of form, which has the advantages which one

Art Unit: 1623

skilled in the art would expect from the change. *Glue Co. v. Upton* (USSC 1878) 97 US 3,24 L Ed. 985. Hence, the cyclodextrin product of the instant claims having a flake-shape does not support patentable subject matter. Also, a person that is familiar with the structure of cyclodextrin would know that a dry cyclodextrin product is porous.

The Majid et al patent discloses utility of the cyclodextrin products thereof for preparation of pharmaceuticals. One would be motivated to combine the Shah et al patent and the Majid et al patent in a rejection of the claims in view of the similar utility of the cyclodextrin products in both patents.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the cyclodextrin product in the Majid et al patent, before being subjected to the agglomeration procedure, with a modified cyclodextrin product in view of the recognition in the art, as evidenced by the Shah et al patent, that the modified cyclodextrin products are effective as clathrating agents with drugs to provide complexes that are useful in pharmaceutical formulations.

Summary

8. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

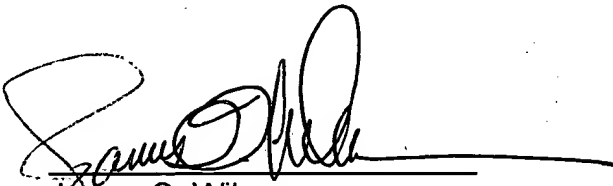
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Art Unit: 1623

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600